QUALITY POLICY: EQUIPMENT

3.0 PURPOSE

To describe how Franciscan Health System Laboratory identifies critical equipment, and in conjunction with the Regional Clinical Engineering Department, ensures that critical equipment is checked for safety, installed, qualified, calibrated, and maintained according to manufacturer's specifications.

3.1 IDENTIFICATION OF CRITICAL EQUIPMENT

- Critical equipment is defined as that equipment that is critical to the provision of laboratory products and services.
- Each laboratory section will have a list of critical equipment.

3.2 EQUIPMENT QUALIFICATION

Before being used for patient testing, equipment is qualified according to a pre-approved qualification protocol. The main goal in qualifying laboratory equipment is to ensure the validity and reproducibility of data. Equipment qualification is often a key initial step in a process or procedure validation and consists of three stages:

- Installation Qualification
- Operational Qualification
- Performance Qualification

A qualification protocol document will be written and approved prior to qualification testing. Final acceptance of the equipment is dependent on completing each qualification successfully, with complete documentation of failures and problem resolutions.

3.3 INSTALLATION QUALIFICATION

Installation qualification establishes that the instrument is delivered as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the instrument. Documented verification that all key aspects of hardware installation adhere to appropriate codes and the computer system specification is required.

Regional Clinical Engineering will do the following:

- Ascertain that equipment is placed in a location that meets with manufacturer's specifications
- Test equipment for compliance with manufacturer specifications

- Test for compliance with safety, electrical, and mechanical standards
- Assign an identification number
- Document the inspection and the date of the inspection
- Place on Equipment Management Inventory List
- Assign a preventative maintenance schedule if appropriate
- Perform preventative maintenance (may be performed by laboratory staff)

3.4 OPERATIONAL QUALIFICATION

Operational qualification is the process of demonstrating that an instrument will function according to the manufacturer's operational specifications under normal laboratory conditions. The qualification may be performed with the aid of manufacturer's technical personnel. The following will be incorporated:

- Analysis of existing documents to determine if revision is required
- Development of any new process or work instruction documents. When applicable Electronic Procedures and Manufacturer provided User Manuals may be used as procedure manuals.
- Paper document copy or current CD is available in case of network /instrument malfunction.
- Calibrations
- Quality control
    - Materials established
    - Frequency determined
    - Ranges set
- The following statistical experiments are performed, documented, approved, and values established for the following:
    - Standard deviation, or coefficient of variation of results in a set of replicate measurements
    - Accuracy
    - Precision
    - Linearity
    - AMR
    - Lower Limit of Detection
- Training and competency for staff on the use of the equipment is complete and documented.

3.4 PERFORMANCE QUALIFICATION

Performance qualification is a testing procedure designed to test the analytical instrument's functional performance to the limits of factory published specifications. It represents the final qualification of the equipment and incorporates a range of testing to

simulate production process options and provide assurance that the equipment is capable of subsequent process validation activities. This phase of equipment qualification is performed solely by laboratory personnel. It must reflect all critical items and satisfactorily challenge them close to the limits of worst-case scenarios as is practical.

Items which may be included according to the type of equipment involved:

- Repeated start-ups and shut-downs to simulate manual, automatic, and emergency conditions
- Confirmation and final verification of work instruction and protocol accuracy
- Testing high through-put levels
- Testing close to temperature limits of instrument
- Testing performed close to detection limits of instrument
- Temperature mapping of monitored storage units.
- Other rigorous testing as suggested by equipment parameters.
- Identification of failures and correction followed by retesting.
- Final determination of indicators which will trigger equipment re-qualification

3.3 CALIBRATION PROGRAM

All instruments are calibrated at the time of installation, as specified in the equipment validation plan. Calibration verification of analyzers is performed with CAP Linearity Survey Material or other commercially available reference material. Subsequent calibration verification of equipment is performed at the following times:

- When indicated by Quality Control Data
- After major maintenance or repair
- When recommended by the manufacturer
- Every 6 months, or as required
- At changes of reagent lots .

3.4 PREVENTIVE MAINTENANCE PROGRAM

Laboratory equipment is maintained by both the Laboratory Staff and the Regional Clinical Engineering Department. Laboratory staff performs periodic maintenance according to a predefined schedule which at a minimum is in accordance with manufacturer's instructions, except for that maintenance requiring trained service technicians. This service technician maintenance is performed by Clinical Engineering or manufacturer's representatives, and documented in an electronic record maintained by the Clinical Engineering Department, with copies provided for manual logs readily available in the Laboratory.

REFERENCES

Food and Drug Administration, Center for Biologics Evaluation and Research, Guideline on General Principles of Process Validation. Rockville, MD: Food and Drug Administration, May 1987